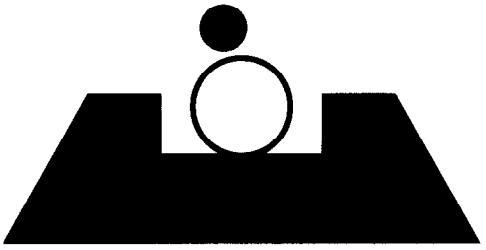

Micro ICU Project

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January 18, 2005

Dr. Steven Galson, Acting Director
Center for Drug Evaluation and Research
Food and Drug Administration
C/o Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: NDA 21-045/S-011

Dear Dr. Galson,

I wish to bring to your attention an important error in the labeling of Plan B.

Dr. James Trussell and colleagues at Princeton University report: "On average, if 100 women have unprotected intercourse once during the second or third week of their cycle, 8 will become pregnant." (1) In recent correspondence with me, Dr. Trussell states that "7 pregnancies are prevented per 100 uses of Plan B, or 1 pregnancy prevented per 14.3 uses." However, an error has been made here because the indications and usage of Plan B by women are not limited to "the second or third week of their cycle" for which these statistics were calculated. As a result of this error, the product labeling for Plan B mistakenly reads (under Clinical Studies): "After a single act of intercourse, the expected pregnancy rate of 8% (with no contraception) was reduced to approximately 1% with Plan B. Thus, Plan B reduced the expected number of pregnancies by 89%." (2) Instead, the expected pregnancy rate is less than 8% when including acts of intercourse taking place outside the second or third week of the cycle. Thus, taking the whole cycle into account, I estimate that the ratio of use to pregnancy reduction for Plan B is roughly on the order of 28 uses per pregnancy reduced. In other words, for every 28 uses of Plan B, one pregnancy is reduced with perfect use. This estimate is reasonable since in general a cycle will last at least twice as long as the two week interval for which Dr. Trussell and colleagues have based their statistics.

In the case of the morning-after pill, the understanding of physicians and researchers remains deeply befuddled. For example, in Resolution 443 (A-04), the House of Delegates of the American Medical Association refers to "[t]he Plan B pill" indiscriminately as either the combination pill form or the progestin-only pill form of the morning-after pill, even though these two distinct forms differ very markedly in their ability to reduce pregnancies; in fact, though once touted, the combination pill form, marketed as Preven, has already been voluntarily withdrawn from the U.S. market. (3, 4) The mistake concerning the labeling of Plan B by Barr Laboratories provides yet another example of serious befuddling; for it should have been completely clear that the rate of ineffectual use associated with Plan B will be far greater than 14.3 uses of Plan B per

pregnancy reduced, since obviously some women would inevitably be using Plan B after intercourse occurring outside of the second or third weeks of their cycles. Indeed, that research surrounding Plan B has been deeply befuddled is well indicated by a recent study that found women given advance provision of Plan B used it twice as much as other women having the same frequency of unprotected intercourse, yet with no increase in the number of pregnancies reduced; although the authors argued for advance provision, their own research shows that advance provision had the effect of doubling the rate of ineffectual use associated with Plan B. (5) Some have fantasized that Plan B will reduce 1.7 million pregnancies annually. (3) But analysis shows that Plan B will actually create an epidemic of unwanted pregnancies in a typical use scenario. However, even to reduce 1.7 million pregnancies with perfect use in a controlled setting, 50 to 100 million units of Plan B would be required, based on the ratio of use to pregnancy reduction, and the fact that advance provision has been found to double the rate of ineffectual use.

Concepticide is the taking of the life of a conceptus. Because the Plan B regimen has a concepticidal component, additional ethical reservations are involved. For example, if a married woman is raped, it would be necessary to warn her that Plan B might destroy a conceptus created between herself and her husband, rather than one created as a consequence of rape. Ethical problems as important as this force us to realize that a purely non-concepticidal means is needed for the good of public health. Yet if illusory infatuation with the morning-after pill is allowed to dominate, research in this direction will be slowed. Thus, an added benefit of closing the door on the ethically problematic and ineffective morning-after pill is that the door to new research will be opened.

If the potential for a few to use a drug on their own with satisfactory results was enough to warrant over-the-counter sales, then no drug would require a prescription. Instead, we must take into account the overall effect on public health. Above all, we must not allow the trend of improving responsibility, especially among teens, to be befuddled by illusory infatuation with the morning-after pill.

Please join me in rejecting Plan B and the outdated consensus supporting it.

Sincerely,

Mr. Eurica Californiaa, Amb.
Juridic Embassy, Micro ICU Project

References:

1. Princeton University. Emergency Contraception. http://ec.princeton.edu/questions/eceffect.html.
2. Plan B. Prescribing Information. http://www.go2planb.com/section/prescribing_info/index.html.
3. American Medical Association House of Delegates. Resolution 443 (A-04) Re: FDA Rejection of Over-The-Counter Status for Emergency Contraception Pills. Jun. 12, 2004.
4. Preven Online Care Center. http://www.preven.com.
5. Raine TR, Harper CC, Rocca CH, Fischer R, Padian N, Klausner JD, Darney PD. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. *JAMA*. 2005 293(1):54-62.